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| 10/524,486 | 11/17/2005 | Stefan Laufer | 264821US0PCT | 6298 |
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APR 18 2008

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

In re Application of:

Stefan Laufer et al.

Serial No.: 10/524,486

Filed: February 14, 2005

Attorney Docket No.: 264821US0PCT

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PETITION DECISION

This is in response to the petition under 37 CFR § 1.181, filed April 1, 2008, requesting that the Advisory Action mailed March 14, 2008, which refuses entry of the claim amendments filed under 37 CFR 1.116 after final Office action on February 26, 2008, be entered.

BACKGROUND

More recently, applicants submitted an amendment after final Office action on February 26, 2008 filed under 37 C.F.R. 1.116. In this amendment, applicants proposed the following amendments to the claims:

- Claim 16, part (b), replacing 'NR⁷COR⁸' with 'NR⁷COR¹⁰,
- Claim 16, the addition of the phrase 'or, if R³ is NR⁷COR¹⁰, is R⁸' (last line of page 2)
- Claim 25, replacing the phrase 'Het is a 5- or 6-membered aromatic heterocycle...' with 'Het is a 5- or 6-membered non-aromatic heterocycle...'

In response to applicants' amendment filed after final Office action on February 26, 2008, the examiner mailed an Advisory Action on March 14, 2008. In this Advisory Action, the examiner indicated that the amendments filed after final Office action on February 26, 2008 would not be entered because they would raise new issues that would require further consideration and/or search, they would raise the issue of new matter and they were not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal (PTOL-303). As an addendum to these indications, the examiner explained that the request for reconsideration had been considered but did not place the application in condition for allowance because:

...the amendment is NON-RESPONSIVE to the final rejection because it FAILS to address any of the rejections. Applicants continue to fail to present a claim to the elected method. Further, applicants have added new matter to the claims which require further consideration. No support can be found for the newly added proviso clause.

In response thereto, applicants filed this petition on April 1, 2008 under 37 CFR § 1.181, requesting entrance of the claim amendments filed after final Office action on February 26, 2008.

DISCUSSION

The petition and the file history have been carefully considered.

In the petition filed on April 1, 2008, applicants argue that the amendment filed under 37 C.F.R. 1.116 on February 26, 2008 should be entered because the amendments to the claims made therein were sought merely to:

- A) correct the 'inadvertent omission in the definition of R¹⁰' in claim 16; that is, to amend NR⁷COR⁸ to read 'NR⁷COR¹⁰', wherein NR⁷COR¹⁰ was previously cited in claim 2 (now cancelled),
- B) correct the inadvertent omission of 'non' prior to the term 'aromatic' in claim 25 which applicants argue was originally present in claim 2, and
- C) add the inadvertently omitted proviso "if R³ is NR⁷COR¹⁰, R¹⁰ is R⁸" which, as applicants argue, was originally present in claim 2. It is noted here that while applicants state in the petition that the amendment to claim 16 incorporates the proviso "if R³ is NR⁷COR¹⁰, R¹⁰ is R⁸", the actual proviso proposed by applicants is "if R³ is NR⁷COR¹⁰, is R⁸" and such was cited in claim 2 (now cancelled).

Prosecution after final rejection is governed by 37 C.F.R. § 1.116 which states, in part:

- (b) After a final rejection or other final action (§ 1.113) in an application or in an ex parte reexamination filed under § 1.510, or an action closing prosecution (§ 1.949) in an inter partes reexamination filed under § 1.913, but before or on the same date of filing an appeal (§ 41.31 or § 41.61 of this title):
 - (1) An amendment may be made canceling claims or complying with any requirement of form expressly set forth in a previous Office action;
 - (2) An amendment presenting rejected claims in better form for consideration on appeal may be admitted; or
 - (3) An amendment touching the merits of the application or patent under reexamination may be admitted upon a showing of good and sufficient reasons why the amendment is necessary and was not earlier presented.

Applicants argue with regard to (A) above:

Had the previous amendment been fully considered by the Examiner, it would have been appropriate to reject both Claims 16 and 25 on grounds of indefiniteness under 35 U.S.C. § 112, second paragraph; and/or failure to comply with the description requirement of 35 U.S.C. § 112, first paragraph. Then, the amendment would have been responsive to such rejection(s), thereby placing the application in better form and reducing the issues for appeal. No new issues would have been raised, since the Examiner was already

informed in the previous amendment that Applicants intended Claims 16 and 25 to be based on Claims 2 and 1, respectively.

Thus, applicants contend that at the time the final Office action was mailed on December 11, 2007, the examiner improperly overlooked that NR⁷COR⁸, present in claim 16, that should have been rejected under 35 U.S.C § 112, first or second paragraph. Applicants therefore assert that said amendment places the claims in better condition for appeal by obviating possible issues under 35 U.S.C MPEP § 112, first and/or second paragraph. However, such contentions by applicants are merely presumptions absent actual rejections of such by the examiner on the record. Further, with regard to this particular amendment, even if the examiner had overlooked rejectionable subject matter with regard to the recitation of NR⁷COR⁸, the change from 'NR⁷COR⁸' to 'NR⁷COR¹⁰', would have required further consideration on the part of the examiner because 'NR⁷COR⁸' was not present in claim 16 at the time the final Office action was mailed, and said change was not specifically suggested by the examiner. While applicants argue that the amendment filed on October 1, 2007 stated that claims 16-24 were 'based on Claims 2-4, 8-11, 13 and 15', this statement found on page 9 of the amendment was properly not read into the claims and subsequently not examined. Therefore, applicants' amendment of claim 16, part (b); replacing 'NR⁷COR⁸' with 'NR⁷COR¹⁰', was not made in response to any specific suggestion by the examiner and it is not determined that this change places the claims in *better* form for appeal, especially considering that this species is not under consideration for examination as it is a non-elected species (applicants elected example 54, which corresponds to wherein R³ is the species of (a) in the claim; NR⁴R¹⁰).

Applicant argues with regard to (2) above:

Nor has any issue of new matter been raised (which the Examiner never identifies), since the corrections sought to be made in Claims 16 and 25 find bases in Claims 2 and 1, respectively. The so-called proviso can be found in original Claim 2, at page 102, lines 3-6 of the application

However, the examiner's statement "applicants have added new matter to the claims which require further consideration. No support can be found for the newly added proviso clause" indicates that the examiner could not find support for the newly added proviso "if R³ is NR⁷COR¹⁰, is R⁸." Therefore, it is determined that the examiner did identify the 'issue of new matter', contrary to applicants' assertions.

Upon mailing the final Office action in an application, prosecution of the application is closed. Entry of proposed amendments to claims when brought before the examiner when prosecution is closed is limited to amendments which clearly place the claims in better form for appeal, or clearly comply with suggestions raised by the examiner or clearly overcome rejections which can be readily interpreted as allowable subject matter without further undue consideration on the part of the examiner. While language added in a claim after final rejection may have been present in a previous claim, the mere presence of that language in a previous claim does not preclude that language from being new matter. On the contrary, the placement and context of the language within the claim as a whole must be evaluated for new matter. If the examiner cannot readily

determine that the placement and context of a newly proposed limitation presented after final rejection in a claim is not new matter, it may 'raise the issue' of new matter. Raising the 'issue' of new matter is not a rejection *per se*. It is merely indicating to applicants that the proposed amendments may be new matter.

Upon thorough evaluation of the case history, it is determined that the proviso "if R³ is NR⁷COR¹⁰ is R⁸" is not new matter as this limitation was present in claim 2 of the original claims. However, the insertion of this proviso would necessitate a new consideration by the examiner because this proviso was not present in the claims prior to the mailing of the final Office action. It is further pointed out that applicants' proposed insertion of the proviso "if R³ is NR⁷COR¹⁰ is R⁸" in claim 16 is deemed not to place the claims in better condition for appeal, because the proviso is unclear. The proviso does not properly state the alternative in an acceptable format such as 'if A is B then C is D' and is therefore confusing.

With regard to applicants' proposed amendment to claim 25 which replaces 'aromatic' with 'non-aromatic', this change would require further consideration by the examiner because this proviso was not present in claim 25 prior to the mailing of the final Office action. Further, this amendment is not deemed to place the claim in better condition for appeal.

Thus, applicants' arguments that "[t]he Examiner is, in effect, penalizing Applicants for the Examiner's failure to raise appropriate grounds of rejection" is unsubstantiated, and no impropriety on the part of the examiner for the non-entrance of the proposed claim amendments can be found.

Applicants further argue:

Nor is it appropriate to refuse entry of the amendment on grounds that it fails to present a claim to the elected method. In a Response to Restriction Requirement filed April 3, 2007, Applicants elected rheumatoid arthritis as a specific disease, in response to the Examiner's requirement, in the restriction requirement entered March 5, 2007, to elect a specific disease. Present Claims 36 and 37 are each dependent claims that limit the inflammatory disorder of the corresponding independent claim to rheumatoid arthritis. Thus, Claims 36 and 37 are claims directed to the elected method. However, even if such claims were not present, it is not seen how failure to present such claims is ground for refusing entry of an after-Final amendment under the present circumstances.

However, it is noted that the examiner did not refuse entry of the amendment due to the examiner's contention that "Applicants continue to fail to present a claim to the elected method" (page 2, Advisory action). This statement made by the examiner is a continuation of #11 of the Advisory action which states "The request for reconsideration has been considered but does NOT place the application in condition for allowance because:..." (emphasis on the Advisory Action form). On the contrary, the reasons for refusing entry of the proposed claim amendments are identified by #3 (a), (b) and (c) of the Advisory Action. Thus, the examiner's statement, "Applicants continue to fail to present a claim to the elected method" is deemed immaterial to the entry or non-entry of the amendment. However, it is pointed out that the examiner's statement has no basis in the MPEP because applicant need not limit their claims to the elected species in order to be responsive to an Office action (see, for example, MPEP § 803.02).

Applicants further argue:

Nor is it appropriate to refuse entry of the amendment on grounds that it is non-responsive to the Final Rejection when the amendment states that Applicants traverse all the rejections of record for reasons stated in the to-be-filed Appeal Brief, which was filed March 4, 2008.

The examiner's statement "the amendment is NON-RESPONSIVE to the final rejection because it FAILS to address any of the rejections" (emphasis in the examiner's original remarks) is found in the continuation of #11 of the Advisory action which states "The request for reconsideration has been considered but does NOT place the application in condition for allowance because:...". Thus, this statement is immaterial to the entry/non-entry of the proposed amendments. Nevertheless, it appears that the examiner inadvertently overlooked the applicants' traversal of the outstanding rejections: In the amendment filed after final Office action on February 26, 2008, applicants specifically stated that the traversal of the rejections of record was found in the Appeal Brief and that said traversal was incorporated into the remarks by reference therein (see page 2 of the Remarks section filed concurrently with the after final amendment of February 26, 2008).

The examiner is expected to consider any relevant arguments which are present in the remarks made after final rejection if they are not solely directed toward proposed amendments which are not entered. It is clear that the examiner did not properly consider applicants' arguments through apparent inadvertent error. A cursory review of the traversal present in the Appeal Brief filed on March 4, 2008 indicates that the traversal therein does not pertain to any of the newly proposed claim amendments which were not entered; but are specifically directed toward the outstanding rejections based upon the examined, elected species and therefore should rightfully be considered.

Applicants' request to enter the proposed claim amendments filed after final Office action on February 28, 2006 is denied. However, it is decided that the Advisory Action mailed by the examiner on March 14, 2008 is incomplete because it does not specifically address applicants' traversal of the currently pending rejections.

DECISION

The petition is **GRANTED IN-PART.**

This application will be forwarded to the examiner to vacate the prior Advisory Action mailed on March 14, 2008 in order to fully consider relevant arguments made by applicants in traversal of the outstanding rejections; said traversal being found in the Appeal Brief filed on March 4, 2008. Entry or non-entry of the claim amendments proposed by applicants in the amendment filed after final Office action on February 26, 2008 is referred to the discretion of the examiner.

Should there be any questions about this decision please contact Marianne C. Seidel, by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0584 or by facsimile sent to the general Office facsimile number, 703-872-9306.

A handwritten signature in black ink, appearing to read "Christopher Low". The signature is stylized with a large, looped "C" and a trailing flourish.

Christopher Low
Director (Acting), Technology Center 1600

DOCKET NO: 264821US0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :
STEFAN LAUFER, ET AL. : EXAMINER: MORRIS, P. L.
SERIAL NO: 10/524,486 :
FILED: NOVEMBER 17, 2005 : GROUP ART UNIT: 1625
FOR: 2-THIO-SUBSTITUTED :
IMIDAZOLE DERIVATIVES AND THEIR
USE IN PHARMACEUTICS

PETITION UNDER 37 CFR 1.181

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicants respectfully petition from the Examiner's refusal to enter, by an Advisory Action entered March 14, 2008, the amendment under 37 CFR 1.116 filed February 26, 2008.

Statement of Facts

In the above-referenced amendment under 37 CFR 1.116 (amendment), Applicants sought to amend Claims 16 and 25. Claim 16 was sought to be amended to correct an inadvertent omission in the definition of R¹⁰. In the previous amendment filed October 1, 2007 (previous amendment), it was stated that Claim 16 was based on Claim 2. Claim 2 recited, *inter alia*, that if R³ is NR⁷COR¹⁰, R¹⁰ is R⁸. Thus, this limitation was sought to be added, as well as correcting "NR⁷COR⁸" to "--NR⁷COR¹⁰--". In the previous amendment, it was stated that Claim 25 was based on Claim 1. Claim 25 was sought to be amended to correct an inadvertent error in the definition of "Het", which is a 5- or 6-membered non-

aromatic heterocycle, as supported by, for example, original Claim 1 and page 6, line 11 of the specification.

In the Advisory Action, the Examiner refuses to enter the amendment on the grounds that:

- (1) it raises new issues that would require further consideration and/or search;
- (2) it raises the issue of new matter; and
- (3) it is not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

In a Continuation Sheet attached to the Advisory Action, the Examiner states that the amendment is non-responsive to the Final Rejection because it fails to address any of the rejections; that Applicants continue to fail to present a claim to the elected method; that Applicants have added new matter to the claims which require further consideration; and no support can be found for the newly added proviso.

Argument

Had the previous amendment been fully considered by the Examiner, it would have been appropriate to reject both Claims 16 and 25 on grounds of indefiniteness under 35 U.S.C. § 112, second paragraph; and/or failure to comply with the description requirement of 35 U.S.C. § 112, first paragraph. Then, the amendment would have been responsive to such rejection(s), thereby placing the application in better form and reducing the issues for appeal. No new issues would have been raised, since the Examiner was already informed in the previous amendment that Applicants intended Claims 16 and 25 to be based on Claims 2 and 1, respectively. Nor has any issue of new matter been raised (which the Examiner never identifies), since the corrections sought to be made in Claims 16 and 25 find bases in Claims

2 and 1, respectively. The so-called proviso can be found in original Claim 2, at page 102, lines 3-6 of the application.

The Examiner is, in effect, penalizing Applicants for the Examiner's failure to raise appropriate grounds of rejection.

Nor is it appropriate to refuse entry of the amendment on grounds that it is non-responsive to the Final Rejection when the amendment states that Applicants traverse all the rejections of record for reasons stated in the to-be-filed Appeal Brief, which was filed March 4, 2008.

Nor is it appropriate to refuse entry of the amendment on grounds that it fails to present a claim to the elected method. In a Response to Restriction Requirement filed April 3, 2007, Applicants elected rheumatoid arthritis as a specific disease, in response to the Examiner's requirement, in the restriction requirement entered March 5, 2007, to elect a specific disease. Present Claims 36 and 37 are each dependent claims that limit the inflammatory disorder of the corresponding independent claim to rheumatoid arthritis. Thus, Claims 36 and 37 are claims directed to the elected method. However, even if such claims were not present, it is not seen how failure to present such claims is ground for refusing entry of an after-Final amendment under the present circumstances.

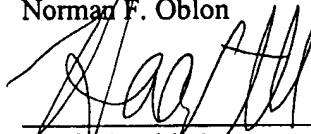
In addition to the reasons presented above for vacating the Examiner's refusal to enter the amendment, Applicants note that an issue has been reached on the patentability of the present invention over the prior art between the Office and Applicants. Entry of the amendment will not cause the Examiner to reconsider the prior art rejection, because the amendment does not go to the merits of the rejection but rather, as discussed above, seeks to correct inadvertent errors. Thus, administrative economy will be served by entering the amendment and permitting the appeal to move forward.

Application No. 10/524,486
Petition under 37 CFR 1.181

Accordingly, it is respectfully requested that the amendment be entered, and that the Appeal Brief, which presumed entry of the amendment, be acted on by the Examiner.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon

A handwritten signature in black ink, appearing to read 'Harris A. Pitlick', is written over a horizontal line.

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